Quill Medical Custom Davice Experience 1993 - 2001

Adverse	•	•	Exposed	•	•	ı	•	-	Broken	•	Broken	Broken	1	-1
Direction of Follow up Adverse	>3 mos.	>3 mos.	<1 mo.	4 mos.	17 mos.	3 пюв.	2 mos.	2 mos.	△ 100.	3 mos.	< <u>1 mo</u> ,	<1 mo.	8 mos.	8 mos.
Number of Outh	1	1	1	2	2	1	1	4	2	7	2	2	7	7
3	L. cheek	R lower eyelid	R lower eyelid	L, R upper lip	L, R brow	R brow	R brow	L, R brow	L, R neck	L, R lower cheek	L, R neck	L, R upper cheek	L, R neck	L, R upper cheek
	M	F	F	M	M	í¥,	F	F	F		<u> </u>		ž.	
	50'8	20.8	20.8	30,8	34	34	28	59	99	,	83		જ	
Procedure	Tisme Sculpting													

9 E			
Advers Reactio	•		
Direction of Follow-up	3 mos.	<1 mo.	
Number of Quill Sutures Used	Þ	1	
118	R breast	Arm	
K	F	M?	
	20'8	40.87	
Protedure	Wound Closure		

Summary:

11 Patients
12 Procedures
30 Quill Sutures Used
77% (23/30) Successfi

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EXHIBIT E

Quill Medical Custom Device Experience

Gregory Ruff, MD of Duke University Medical Center designed the Quill Medical suture concept in response to specific plastic and reconstructive surgical needs for specific patients presenting to Dr. Ruff's practice beginning in early 1993.

Quill sutures were made by hand from 1993 until 2000 utilizing Ethicon PDS II suture sizes 0 or 1. Dr. Ruff cut the initial Quill sutures during surgery with a #15 scalpel blade into the Ethicon PDS II sutures that were clamped over a flat-bottomed basin in a sterile field. Initially the barb configuration was designed as a spiral array around the long axis of the suture though imprecision of the hand-cutting technique ultimately created a random pattern.

During 2000, Quill Medical sutures were created prior to surgery by cutting barbs into Ethicon PDS II size 0 sutures using a prototype machine. The barbed sutures' ends were swaged with a second needle after outting the barbs. The barbed needled sutures were then resterilized using a standard ETO sterilization cycle.

The details of Dr. Ruff's custom device experience with custom Quill Medical suture are presented in Tab 1.

In summary, twenty-nine (29) custom Quill sutures were used in 10 patients undergoing twelve (12) Plastic and Reconstructive surgical procedures over a period about 9 years. The custom Quill sutures have been used in a variety of ways to rearrange intact tissue as well as in the closure of cutaneous and deeper wounds. Quill sutures were successful in 22/29 (76%) uses and failed in 7/29 (24%) uses. Exposure of the barbed suture was the only complication which troubled any patient. This occurred once in very thin skin into which Quill suture was placed very superficially and later in two patients in whom the manufacturing process was thought to have weakened the Quill suture at its transition point resulting in breakage thereof with post-operative animation of the face and neck. This custom Quill suture experience suggests that Quill sutures will be well tolerated when placed deep to the reticular dermis and manufactured as designed.

Quill Medical Suture Custom Device Experience 1993 – 2000

Patients	10			
Procedures	12			
Quill Sutures Used	29			
Successful	76% (22/29)			
Failed	24% (7/29)			

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